

Applicant : Andres Belalcazar et al.
Serial No. : 10/726,949
Filed : December 3, 2003
Page : 8 of 13

Attorney's Docket No.: 09531-157001 / Z04067

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Remarks

In the non-final office action mailed March 31, 2006, the Examiner rejected claims 1-43. The Applicant has amended claim 13. As such, claims 1-43 are pending. The Applicants respectfully request the Examiner's reconsideration in view of the amendments and arguments set forth in this response.

The undersigned thanks the Examiner for courtesies extended during a telephone interview held on June 16, 2006. Applicants agree that the Examiner's Interview Summary mailed on June 20, 2006 accurately documents the interview.

CLAIM REJECTION – 35 USC 112

The office action rejected claim 13 under 35 U.S.C. 112(1) as failing to comply with the enablement requirement. The claim has been amended to recite a physically correct relationship between voltage, current, and impedance. The amendment corrects an error of a clerical nature, and is not made for reasons related to patentability. The amended claim finds support at least in the originally filed specification at paragraph [0058] and in original claim 35. As such, no new matter has been added by this amendment.

CLAIM REJECTIONS – 35 USC 102/103

The office action rejected claims 22, 28, 29, 32-35, and 41 as anticipated under 35 U.S.C. 102(b) by U.S. Pat. 6,370,424 to Prutchi ("the Prutchi reference"). The office action rejected claims 1-4, 7-12, 14-21, 23-25, 30, 31, 36-40, 42, and 43 as obvious under 35 U.S.C. 103(a) by the Prutchi reference in view of U.S. Pat. 6,595,627 to Pitts-Crick et al. ("the Pitts-Crick reference"). The office action also rejected claims 5, 6, 26, 27 as obvious under 35 U.S.C. 103(a) by the Prutchi reference in view of the Pitts-Crick reference and further in view of U.S. Pat. 6,473,640 to Erlebacher. Claims 1 and 22 are independent.

As discussed in the interview, Applicants submit that independent claims 1 and 22 define subject matter that is patentable over the cited references.

Applicant : Andres Belalcazar et al.
Serial No. : 10/726,949
Filed : December 3, 2003
Page : 9 of 13

Attorney's Docket No.: 09531-157001 / Z04067

Applicants' claims are directed to methods and apparatus for detecting changes in fluid volume in a thoracic region, such as the lung, by internally injecting a current through the region, detecting an induced voltage on the skin of the patient, and calculating an impedance value. (Abstract.) In other words, the claims are directed to assess body fluid by making a single impedance measurement based on an externally detected voltage signal that is induced by an internally injected current signal.

The Prutchi reference is instead directed to preventing interference between an internal impedance measurement and a separate external impedance measurements by synchronizing them so that they don't occur at the same time. The Prutchi reference discloses making an external impedance measurement using a cardiorespiratory monitor that generates and detects bioimpedance signals using externally injected current and externally detected voltage. Col. 6, lns. 13 – 24. For patients who have an implanted medical device, Prutchi describes making an internal impedance measurement using internally injected current and internally detected voltage. Col. 8, lns. 36 - 50. The system described by the Prutchi reference times the external impedance measurements so that the external impedance sensing signal does not interfere with the impedance sensing signal delivered by the implanted device. Col. 6, lns. 41-54. The Prutchi reference makes clear that the external and internal impedance measurements are made entirely separately. For example, a primary thrust of the Prutchi disclosure is to control the timing of the external impedance measurement so that the external impedance signals will produce substantially no interference with the internal signals generated by implanted devices. (Abstract.) Specifically, the cardiorespiratory monitor determines the frequency and timing of the micropulses emitted by the implanted device and uses this information to time the delivery of its own impedance sensing signal so as not to coincide with the impedance sensing signal delivered by the implanted device. Col. 6, lns. 46-51. In fact, the Prutchi reference teaches that cross-interference between an external impedance cardiograph device and an internal impedance-measuring cardiac stimulator may cause inaccurate measurements and less than ideal operation. Col. 5, lns. 1-15.

Applicant : Andres Belalcazar et al.
Serial No. : 10/726,949
Filed : December 3, 2003
Page : 10 of 13

Attorney's Docket No.: 09531-157001 / 204067

As the Examiner correctly points out, the Pitts-Crick reference discloses a system that senses the trans-thoracic impedance, which is dependent on the fluid content of the lungs, to assist in the detection and quantification of pulmonary edema and thus pulmonary congestion. Col. 12, lns. 31-37. The Pitts-Crick reference discloses impedance measurement using internal electrodes of implantable electrical devices. Col. 11, lns. 4-6.

Neither of the cited references, when taken alone or together, teaches or suggests calculating an impedance as recited in Applicants' claim 1 or claim 22. For example, neither reference suggests or even contemplates making impedance measurements based on an externally detected voltage signal that is induced by an internally injected current signal, as required by both independent claims.

Turning first to Applicants' independent claim 1, none of the references, either alone or in combination, teaches or suggests the recited method steps of injecting an electrical current between first and second internal electrodes, measuring a voltage between first and second external electrodes, and calculating an impedance by taking the ratio of the measured voltage and the injected current. For example, the Prutchi reference does not disclose calculating an impedance by taking the ratio of a measured voltage and an injected current, where the voltage is measured between first and second external electrodes and the current is injected between internal electrodes, as recited in Applicants' claim 1. Furthermore, the Prutchi reference does not disclose, and the Examiner has not even contended that it does disclose, that the externally measured voltage used in the impedance calculation is induced by the internally injected current used in the impedance calculation, as recited in Applicants' claim 1.

Turning next to Applicants' independent claim 22, none of the references, either alone or in combination, teaches or suggests the claimed apparatus that includes a receiver that receives information about an electrical current injected between first and second internal electrodes implanted in the body, an interface that receives a voltage signal detected by first and second external electrodes attached to an external surface of the skin of the body, the detected voltage being induced by the injected current, and a processing unit that calculates an impedance from the voltage signal and received information about the injected current.

Applicant : Andres Belalcazar et al.
Serial No. : 10/726,949
Filed : December 3, 2003
Page : 11 of 13.

Attorney's Docket No.: 09531-157001 / Z04067

Contrary to the Examiner's contention, the Prutchi reference simply does not teach or suggest "an interface that receives a voltage signal detected by first and second external electrodes ..., the detected voltage being induced by the injected current." Office Action at pg. 3. Applicants' claim 22 requires that the injected current be "injected between ... internal electrodes ... implanted in the body." Rather than measuring impedance based on the external voltage that is induced by an internally injected current, as recited in Applicants' claim 22, the Prutchi reference teaches an external voltage that is induced by an externally injected current. Furthermore, and as discussed above, the Prutchi reference discloses separate internal and external impedance measurement systems that are timed to operate so that the internal and external signals don't interfere with each other.

In addition, and contrary the Examiner's contention, the Prutchi reference does not disclose "a processing unit that is capable of determining the fluid volume in the region by calculating a first impedance from the voltage signal and the received information about the injected current." Office Action at pg. 3. Applicants' claim 22 requires a processing unit that determines fluid volume by calculating the impedance from an externally received voltage signal that is induced by an internally injected current. In contrast to Applicants' claim, the system described in the Prutchi reference controls the timing of impedance measurement signals so that the external voltage signals used to measure impedance are not induced by internally injected current signals. Moreover, there is no teaching or recognition in the Prutchi reference to enable or even suggest a processing unit with, for example, suitable programming to achieve the apparatus of Applicants' claim 22.

The Pitts-Crick reference does not remedy the deficiencies of the Prutchi reference, and the Examiner has not alleged that it does. For example, the Pitts-Cricks reference does not teach or suggest making impedance measurements based on an externally detected voltage signal that is induced by an internally injected current signal, as recited in Applicants' claim 1 and claim 22.

Neither do the cited references, either alone or in combination, render the independent claims 1 and 22 obvious. For example, Applicants' impedance measurement approach using internal current injection and external voltage measurement is very different from past

Applicant : Andres Belalcazar et al.
Serial No. : 10/726,949
Filed : December 3, 2003
Page : 12 of 13

Attorney's Docket No.: 09531-157001 / Z04067

approaches, and it yields various important benefits that are not offered by the prior art. Figure 4, for example, shows computer simulation studies that were performed on human thoracic models. These studies show the good results that may be achieved for an implementation of Applicants' approach. For example, those results show that the hybrid approach of using internal current injection and external electrodes can be expected to perform about as well as the all-implantable approach. In addition, Applicants' approach may be used, for example, with currently deployed implantable medical devices that otherwise lack the capability to measure organ impedance. Also, because Applicants' approach uses electrodes implanted in fixed locations, Applicants' approach provides for consistency in the location of the current injection from one measurement to the next (which measurements may be, for example, months apart). As such, changes from one measurement to the next are more of an apples to apples comparison, and provide for a more accurate monitoring of the lung fluid condition over a long period of time. At the same time, Applicants' approach of using external voltage detection gives some flexibility in the placement of the electrodes at locations so that the lung tissue of interest is directly between the electrodes.

Accordingly, independent claims 1 and 22 are patentable over the cited references. As such, dependent claims 2-21 and 23-43 are also patentable over the cited references. Applicants submit that claims 1-43 are in condition for allowance, and respectfully request that the Examiner remove the rejections as to each of these claims.

CONCLUSIONS:

Applicants respectfully request that the Examiner consider the pending claims, and promptly issue a notice of allowance of all claims 1-43.

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as

Applicant : Andres Belalcazar et al.
Serial No. : 10/726,949
Filed : December 3, 2003
Page : 13 of 13

Attorney's Docket No.: 09531-157001 / Z04067

an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

No fee is believed to be necessary. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,



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